Zalgen

January 2021

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Who we are.

Zalgen's vision is to serve all people—regardless of ethnicity, income status, or nationality—to create a world where every person can live free without the fear of deadly infectious diseases that could claim their lives.

Leadership

Dr. Luis Branco
Managing Director and Co-Founder
PhD (Tulane University)
BS (University of Massachusetts at Amherst)

Dr. Robert F. Garry, Jr
Co-Founder and Chairman, Scientific Advisory Board
Tulane University, Professor of Microbiology and Immunology
PhD (University of Texas)
BS (Indiana State University)

Facilities

Headquarters and
Biotechnology Operations
Germantown, MD

Diagnostic Product
Development Center
Aurora, CO

Clinical & Research Affiliates

Tulane University
New Orleans, LA

Kenema Government Hospital
Kenema, Sierra Leone

University of Texas
Medical Branch
Galveston National Laboratory
Galveston, TX

Redeemer's University
Ede, Nigeria

Accomplishments

- First-in-class immunotherapeutic specifically designed to treat acute Lassa infections
- First rapid diagnostic test for Ebola to receive both FDA Emergency Use Authorization (EUA) and WHO Emergency Listing Approval
- First (and only) rapid diagnostic test for Lassa to be CE Marked
- Extensive unique line of immunodiagnostics for detection of acute Pan-Lassa infections and for characterization of the post acute humoral immune response
- E-commerce platform for commercialization of VHF reagents and diagnostic kits
- Peer reviewed publications in high impact scientific journals

Vertically Integrated

Cutting edge immunotherapeutic technology

Scientific & industry collaboration

Patented recombinant processes

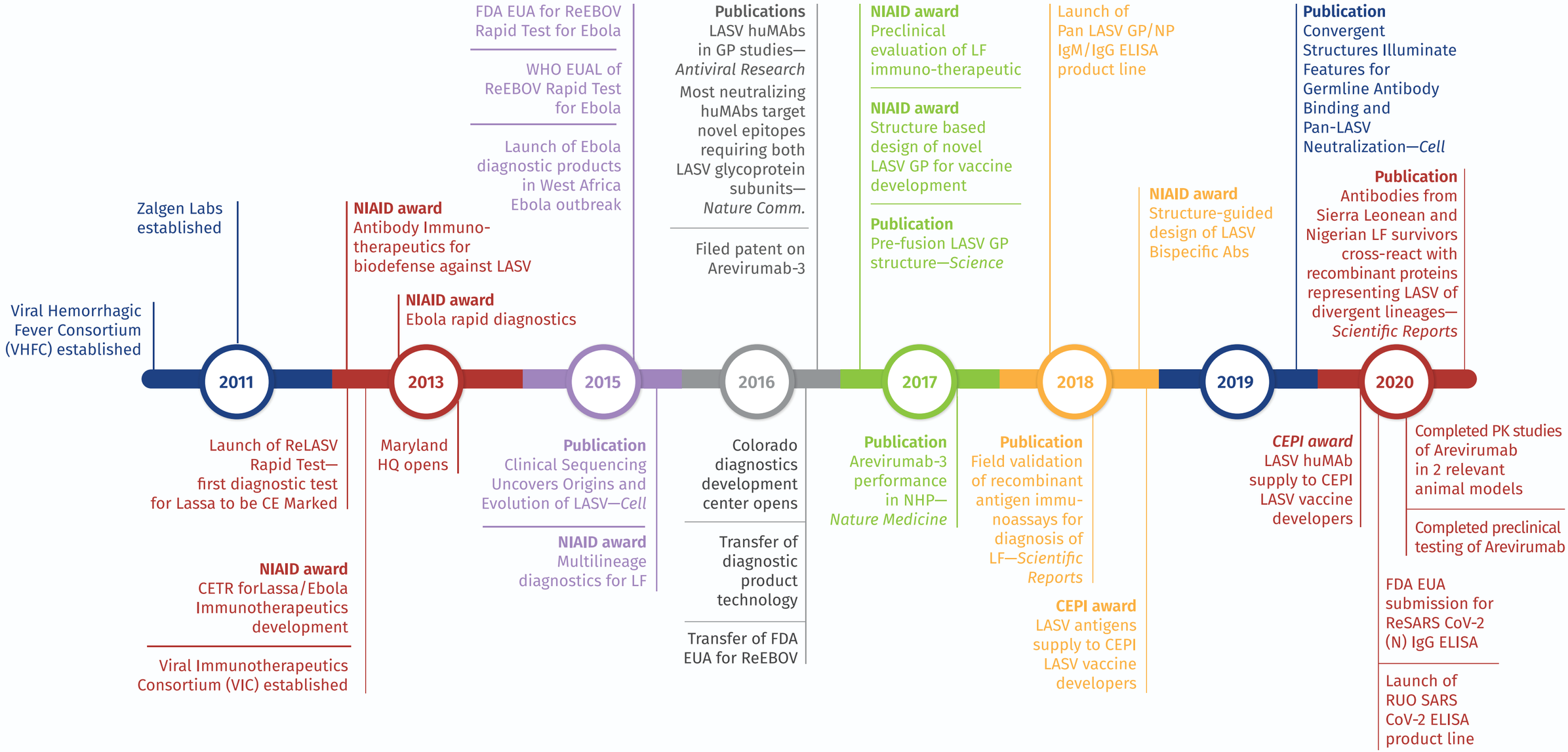
Partnering capabilities

Expanding global commercialization & distribution

Most extensive line of VHF diagnostics

Well-established infrastructure

Milestones


Viral Hemorrhagic Fever Consortium (VHFC) established
Zalgen Labs established
2011
Launch of ReLASV Rapid Test—first diagnostic test for Lassa to be CE Marked
NIAID award
CETR forLassa/Ebola Immunotherapeutics development
Viral Immunotherapeutics Consortium (VIC) established
NIAID award
Antibody Immuno-therapeutics for biodefense against LASV
NIAID award
Ebola rapid diagnostics
2013
Maryland HQ opens
FDA EUA for ReEBOV Rapid Test for Ebola
WHO EUAL of ReEBOV Rapid Test for Ebola
Launch of Ebola diagnostic products in West Africa Ebola outbreak
2015
Publication
Clinical Sequencing Uncovers Origins and Evolution of LASV—Cell
NIAID award
Multilineage diagnostics for LF
Publications
LASV huMAbs in GP studies—Antiviral Research
Most neutralizing huMAbs target novel epitopes requiring both LASV glycoprotein subunits—Nature Comm.
Filed patent on Arevirumab-3
2016
Colorado diagnostics development center opens
Transfer of diagnostic product technology
Transfer of FDA EUA for ReEBOV
NIAID award
Preclinical evaluation of LF immuno-therapeutic
NIAID award
Structure based design of novel LASV GP for vaccine development
Publication
Pre-fusion LASV GP structure—Science
2017
Publication
Arevirumab-3 performance in NHP—Nature Medicine
Launch of Pan LASV GP/NP IgM/IgG ELISA product line
Publication
Field validation of recombinant antigen immu-noassays for diagnosis of LF—Scientific Reports
CEPI award
LASV antigens supply to CEPI LASV vaccine developers
2018
NIAID award
Structure-guided design of LASV Bispecific Abs
2019
CEPI award
LASV huMAb supply to CEPI LASV vaccine developers
Publication
Convergent Structures Illuminate Features for Germline Antibody Binding and Pan-LASV Neutralization—Cell
Publication
Antibodies from Sierra Leonean and Nigerian LF survivors cross-react with recombinant proteins representing LASV of divergent lineages—Scientific Reports
2020
Completed PK studies of Arevirumab in 2 relevant animal models
Completed preclinical testing of Arevirumab
FDA EUA submission for ReSARS CoV-2 (N) IgG ELISA
Launch of RUO SARS CoV-2 ELISA product line

Affiliations

VIRAL
HEMORRHAGIC FEVER
CONSORTIUM

Viral Hemorrhagic Fever
Immunotherapeutic Consortium

Programs

Lassa Fever

- Lassa virus (LASV, family Arenaviridae), the etiologicagent of Lassa fever (LF)
- Endemic throughout WestAfrica; can quickly progress to severe viral hemorrhagic fever (VHF) with mortality rates>50%
- Transmitted to humans by rodents (Mastomys natalensis)
- Mutates quickly necessitating ongoing surveillance
- Classified as NIAID Category A pathogen due to high lethality, ease of transmission and potential for aerosol infection; easily weaponizable
- Elevated level of awareness; selected by Coalition for Epidemic Preparedness Innovation (CEPI) initiative for an accelerated vaccine development program
- Significant pandemic risk

Strategic Priorities

Immunotherapeutics Program	• File an IND and initiate Phase I studies of Arevirumab-3, our first-in-class fully human monoclonal antibody cocktail specifically designed for the prevention and treatment of acute Lassa fever infections • Advance to preclinical testing additional human monoclonal antibodies in our existing portfolio directed against Lassa and Ebola viruses
Vaccine Program	• Advance selected LASV GPC constructs from our proprietary library through validation and scale-up to assess immunogenicity and vaccine efficacy in two animal models; down-select prime vaccine candidates for pre-clinical evaluation as a first-in-class multivalent vaccine for all circulating lineages of Lassa and Ebola viruses
Diagnostic Program	• Enhance our position as global leader for hemorrhagic fever immunodiagnostic tests by securing additional regulatory approvals and building market presence • Expand our diagnostic product portfolio with additional products for detection of acute viremias (circulating antigens) and human convalescent immuneresponses (IgM/IgG) to support immunotherapeutic and vaccine research

Immunotherapeutics Program

Zalgen has core competency in the development of multiple platforms for generation of high quality recombinant proteins from difficult-to-express genes.

- Our proven approaches are supported by the successful development of first-in-class immunotherapeutics for prophylaxis and treatment of Lassa Hemorrhagic Fever. The first three fully human monoclonal antibodies, administered in single or cocktail formats have demonstrated remarkable efficacy in relevant animal models in BiosafetyLevel-4(BSL-4) settings.

- Our efforts are revolutionizing the understanding of epidemiological, immunological, and basic research notions in hemorrhagic viruses, thus contributing to dramatic improvements in the management and successful outcome of these viral diseases

Arevirumab-3 Project

Project Goal: To advance Arevirumab-3 through IND and into Phase 1 testing.

- First in class immunotherapeutic to combat Lassa fever
- Fully human monoclonal antibodies (huMAbs); sequences patent pending
- Arevirumab-3 neutralizes the Lassa virus; exact mechanism TBD
- Testing in two (2) relevant animal models completed
- Published NHP studies in BSL4 facility demonstrated 100% effectiveness against acutely ill infected animals
- Positioned to complete pre-clinical testing and IND submission
- Ideal drug candidate for approval for compassionate use approval; eligible for Priority Review Voucher
- Significant market opportunity:
  - Lassa fever endemic region of West Africa surpasses 220million people
  - US Strategic National Stockpiling(SNS)
  - High containment laboratories
  - International relief organizations conducting medical diplomacy missions in the endemic Lassa fever zone

Arevirumab-3 Milestones

Reformulation of BNhMAb cocktail with alternative hMAbs with better clinical profile if any are identified through ongoing structural and mechanistic studies

36 Months

Milestone 1
Optimization of dose, combination, dosing interval

Complete protection w/ optimized theraemergencepeutic, no MARM *in vivo*

Milestone 2
Chemistry, Manufacturing and Control Data (CMC)

Product manufacturing supports clinical development

Milestone 3
Preclinical Pharmacology & Toxicology of Arevirumab-3

Progression toward clinical development and IND

Vaccine Program

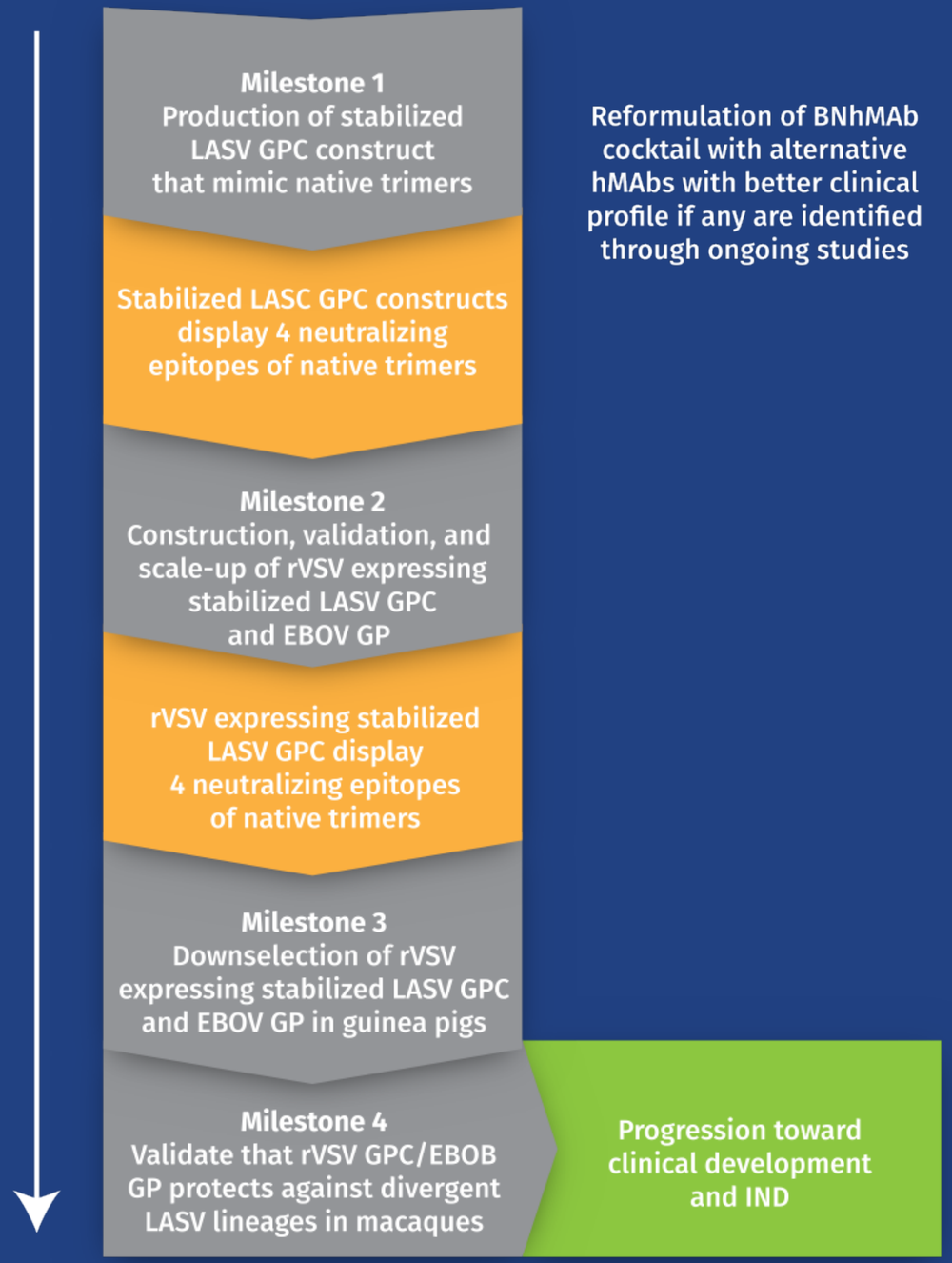
Zalgen has an active, milestone-driven research program utilizing structure-based vaccine design approaches to generate candidate vaccine immunogens against LASV.

- We have demonstrated that the prefusion virion configuration (native) is the structure to which the most important humoral immune responses (antibody-mediated) are directed.
- Our antigens faithfully mimic the native, functional trimers that are present on the LASV surface. We employ structure-based design to stabilize this structure, limiting conversion to post fusion states that fail to elicit protective immune responses, while minimizing generation of non-protective antibodies.
- There are no approved vaccines or therapeutics for human use, and the potential for geographic expansion, ease of procurement and weaponization of the virus necessitate development of broadly reactive fast-acting protective vaccines.

Lassa Fever Vaccine

36 Months

Project Goal: To develop and test an effective dual vaccine platform to LASV and EBOV, and perform critical pre-clinical studies



Diagnostics Program

Zalgen is the global leader in immunodiagnostic products for hemorrhagic fever viruses, not only for use in clinical settings but to support immunotherapeutic and vaccine research along with development.

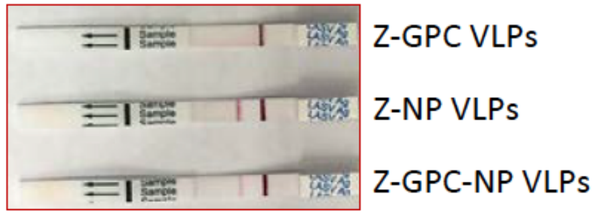
- Our assays include antigen detection as well as IgG/IgM antibody detection of viral agents including Lassa (LASV) and Ebola (EBOV). Additional projects in development include Junín (JUNV), Marburg (MARV) and Dengue (DENV).

- Our ReEBOV® Antigen Rapid Test, a 15-minute test for Ebola virus VP40 antigen, is the first and only rapid Ebola test to receive both FDA Emergency Use Authorization and WHO Emergency Listing. Our ReLASV® Lassa Rapid Test is a 15-minute test for Lassa virus NP, is the first and only Lassa virus rapid test to be CE marked.

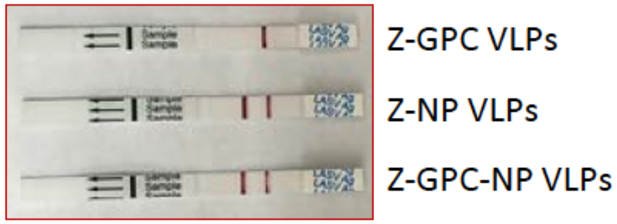
- We are continuing to expand our diagnostic product offerings using both lateral flow immunoassay (LFI) and ELISA microplate delivery platforms to meet the global market needs.

Lassa Diagnostics

Project Goal: To expand Lassa diagnostic product portfolio by completing development and advancing to global commercialization a highly sensitive and specific rapid diagnostic test (RDT) detecting all circulating lineages of Lassa virus.



LASV237-Nigeria 2010H (Lineage II) VLPs analyzed on Pan LASV RDTs (detects Lineages II, III, IV, Mali, Togo)



LASV-Nig08-A18-Nigeria 2008H (Lineage III) VLPs analyzed on Pan LASV RDTs (detects Lineages II, III, IV, Mali, Togo)

12 Months

Milestone 1
Optimization of formulation, analytical specificity & sensitivity

Analytical specifications in line with historical parameters

Milestone 2
Clinical sepcificity & senstitivity using banked sera/plasma

Clinical specificity & sensitivity w/ acute clinical samples vs. QPCR 90%

Milestone 3
Dossier for CE Marking, NAFDAC submission

Implement global commercialization plan

Program Status

Monoclonal antibody-based therapeutics development programs

Target	Discovery	Lead Selection *in vivo*	Pre-Clinical	Collaborators	Funding
Lassa virus				Tulane*, UTMB	NIH/NIAID
Pan Arenavirus				TSRI*, Tulane, UTMB, VIC	NIH/NIAID
LCMV**				TSRI, Tulane, UROCH	NIH/NIAID
Ebola virus				Tulane*, UTMB	NIH/NIAID

Diagnostics development programs

Target	Discovery	Field Validation	CE	Approved WHO[1]/FDA[1]	Collaborators	Funding
ReLASV RDT**					Tulane	NIH/NIAID
Pan Lassa virus**					Tulane	NIH/NIAID
ReEBOV RDT**					Tulane, UTMB, TSRI	NIH/NIAID/ BMGF
ReSARS COV-2					Tulane	–

Vaccine development programs

Target	Discovery	Lead Selection *in vivo*	Pre-Clinical	Collaborators	Funding
Lassa/Ebola virus				Tulane*, UTMB, TSRI, Burnham	NIH/NIAID

** Prime awardee ** Zalgen prime awardee [1] Emergency Use Authorization*

Commercialization

- Lassa testing platforms (Research Use Only): Pan-Lassa Antigen RDT, Lineage IV Antigen RDT, Pan-Lassa Antigen ELISA, Pan-Lassa IgG/IgM ELISA, Single Lineage LASV IgG ELISA
- Ebola testing platforms (Research Use Only): EBOV Antigen RDT, EBOV Antigen ELISA, EBOV IgG/IgM ELISA
- SARS CoV-2 testing platforms (Research Use Only): SARS CoV-2 N protein IgG ELISA, SARS CoV-2 S-RBD protein IgG ELISA, SARS N and RBD proteins
- 18 human monoclonal antibodies specific to LASV GPC or subunits (GP1 and GP2), with defined research applications
- Virus-like particles (VLP), from LASV lineages II,III (Nigeria), IV (SLE, GIN, LBR)

Future Programs

- Zalgen and its partners have derived superior human monoclonal antibodies with therapeutic potential for Lassa fever, Junin, and Ebola; future immunotherapeutic programs may focus on employing the same technology to identify and characterize antibodies to additional, highly relevant and high value infectious agents
- Our extensive experience in developing highly sensitive, specific, and clinically relevant immunodiagnostics maybe applied in future development programs to address unmet needs in the infectious agents arena

Zalgen

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